



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

March 28, 2016

Jamin Huang, Ph.D.
Senior Regulatory Manager
Bayer Crop Science LP
P.O. Box 12014
2 T.W. Alexander Drive
Research Triangle Park, NC 27709

Subject: Label Amendment – Corrects “in-furrow application” to be “seed piece treatment” in Directions for Use for potato seed piece treatment; Updates First Aid and Container Handling statements; Other minor revisions
Product Name: Emesto Silver
EPA Registration Number: 264-1123
Application Date: 01/21/2016
Decision Number: 513372

Dear Dr. Huang:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. “To distribute or sell” is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA’s Office of Enforcement and Compliance.

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Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Kiryssa Kasprzyk by phone at 703-347-8429, or via email at kasprzyk.kiryssa@epa.gov.

Sincerely,

A handwritten signature in black ink that reads "Tony Kish". The signature is written in a cursive style with a large, looped "T" and "K".

Tony Kish, Product Manager 22
Fungicide Branch
Registration Division (7505P)
Office of Pesticide Programs

Enclosure

ACCEPTED

03/28/2016

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 264-1123

Emesto Silver

For use as a fungicide seed dressing for protection against listed seedborne and soilborne diseases in potatoes and wheat.

ACTIVE INGREDIENT:

Penflufen9.35%
Prothioconazole.....1.68%

OTHER INGREDIENTS:88.97%

TOTAL:100.0%

Contains 0.83 lb Penflufen and 0.15 lb Prothioconazole per gallon (100 g Penflufen and 18 g Prothioconazole per liter)

EPA Reg. No. 264-1123

EPA Est.

KEEP OUT OF REACH OF CHILDREN CAUTION

For MEDICAL and TRANSPORTATION Emergencies ONLY Call 24 Hours A Day 1-800-334-7577
For PRODUCT USE Information Call 1-866-99BAYER (1-866-992-2937)

FIRST AID

IF SWALLOWED:	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to by a poison control center or doctor. • Do not give anything to an unconscious person.
IF ON SKIN	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
<p>In case of emergency call toll free the Bayer CropScience Emergency Response Telephone No. 1-800-334-7577. Have a product container or label with you when calling a poison control center or doctor, or going for treatment.</p>	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Harmful if swallowed. Harmful if absorbed through the skin. Avoid contact with skin, eyes, or clothing.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Some materials that are chemical-resistant to this product are barrier laminate, butyl rubber, nitrile rubber, neoprene rubber, polyvinyl chloride, or viton. If you want more options, follow the instructions for category C on an EPA chemical-resistance category selection chart.

All mixers, loaders, applicators and other handlers must wear:

- long sleeved shirt and long pants,
- socks plus shoes,
- chemical resistant gloves, except when bagging or sewing bags of treated seeds,

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS

Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish, aquatic invertebrates, and freshwater/estuaries/marine aquatic plants. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Runoff may be hazardous to aquatic organisms in water adjacent to treated areas. Do not contaminate water when disposing of equipment washwater or rinsate. Treated seed exposed on soil surface may be hazardous to wildlife. Cover or collect seed spilled during loading.

This product has properties and characteristics associated with chemicals detected in ground water. This chemical may leach into ground water if used in areas where soils are permeable, particularly where the water table is shallow. Therefore contain any product spills or equipment leaks and dispose of wastes according to the disposal instructions on this label.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

For use only in commercial seed treatment equipment. Not for use in hopper box, planter box, slurry box, or other on-farm seed treatment applications except for potato seed pieces.

The Agricultural Use Requirements statements below are specific to the potato seed piece use.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard. Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours. Exception: if the product is soil-injected or soil-incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated. PPE required for early reentry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is: coveralls, chemical resistant gloves made of any waterproof material, and shoes plus socks.

POTATO SEED PIECE TREATMENT

CROP	DISEASE	APPLICATION RATE FOR SEED PIECE	DIRECTIONS
<p>Potato (seed piece application)</p>	<p>Black scurf, stem & stolon canker, caused by seedborne and soilborne (suppression) <i>Rhizoctonia solani</i></p> <p>Silver scurf caused by seedborne <i>Helminthosporium solani</i> (suppression)</p> <p>Seed piece rot caused by <i>Fusarium</i> (suppression)</p>	<p>Apply 0.31 fl oz per 100 lbs of seed pieces</p> <p>Maximum number of application per year is 3.</p>	<p>For disease control, good coverage of the seed piece is required.</p> <p>Apply specified dosage as a diluted spray slurry using equipment that ensures uniform coverage of each seed piece. Do not apply more than 2.5 fl oz of slurry / 100 lbs of seed pieces. Apply only in areas with adequate ventilation or in areas that are equipped to remove spray mist or dust.</p> <p>As part of the seed cutting and treating process, application of an inert absorbent ingredient is recommended to improve suberization. For added <i>Fusarium</i> protection apply a Mancozeb containing product specifically designed for application to potatoes in place of the inert absorbent.</p> <p>Do not use treated seed pieces for food, feed, or fodder.</p> <p>Do not exceed more than 0.143 lbs of active ingredient/A (65 g ai/A) per crop season for seed piece treatment.</p>

COMMERCIAL SEED TREATMENT

CROP	DISEASE	APPLICATION RATE	DIRECTIONS
<p>Wheat</p>	<p>Loose smut</p> <p>Seed rot, pre-emergence damping-off and seedling blight caused by soilborne <i>Rhizoctonia solani</i>,</p> <p>Seed decay</p>	<p>Apply 0.75 fl oz per 100 lbs seed</p> <p>Maximum number of application per year is 3.</p>	<p>Apply using commercial slurry or mist-type seed treatment equipment. Uniform application of seed is necessary to ensure seed safety and best disease protection. Dilute product with sufficient water to ensure complete seed coverage. Use high quality, properly cleaned seed.</p>

SEED BAG TAG

The Federal Seed Act requires that the container of seed treated with Emesto Silver must be labeled with the following statements:

- This seed has been treated with Emesto Silver which contains Prothioconazole and Penflufen.
- Do not use treated seed for food, feed, or oil production. Excess treated seed may be used for ethanol production only if (1) by-products are not used for livestock feed and (2) no measurable residues of pesticide remain in ethanol by-products that are used in agronomic practice.
- User is responsible for ensuring that the seed bag meets all the requirements under the Federal Seed Act.

In addition, the US Environmental Protection Agency requires the following statements on the container of seed treated with Emesto Silver:

- Store away from feeds and foodstuffs
- Wear long sleeved shirt, long pants, shoes, socks, and chemical resistant gloves when handling treated seed
- Crops for which there are registered uses of Penflufen, which includes alfalfa; potatoes (Crop Subgroup 1C); legume vegetables (Crop Group 6/7); cereal grains (Crop Group 15/16); and oil seeds (Crop Group 20) may be replanted at any time. All other crops may be planted no less than 30 days after planting treated seeds.
- After the seeds have been planted, do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 12 hours. Exception: Once the seeds are planted in soil or other planting media, the Worker Protection Standard allows worker to enter the treated area without restriction if there will be no worker contact with the treated seeds in the soil or planting media.
- Dispose of all excess treated seed. Left over treated seed may be double sown around the headland or buried away from water sources in accordance with local requirements. Do not contaminate water bodies when disposing of planting equipment washwaters.
- Dispose of seed packaging in accordance with local requirements.
- Use planting equipment that will plant treated seed into the soil to a minimum depth of 0.5 inch.
- This compound is toxic to birds and mammals. Treated seed exposed on soil surface may be hazardous to birds and mammals. Cover or collect seeds spilled during loading.
- Do not use treated seed pieces for food, feed, or fodder.
- For potatoes: Do not exceed 0.143 lb. Penflufen /A (65 g ai/A) per crop season. The maximum number of applications per year is 3. This seed has been treated with xx mg active ingredients (ai) of Emesto Silver /seed which includes Penflufen (2 g ai/100 Kg seed) and prothioconazole (0.36 g ai/100 Kg seed)
- For wheat: Do not exceed 0.0078 lb. Penflufen /A (3.5 g ai/A) per crop season. The maximum number of applications per year is 3. This seed has been treated with xx mg active ingredients (ai) of Emesto Silver /seed which includes Penflufen (4.9 g ai/100 Kg seed) and prothioconazole (0.88 g ai/100 Kg seed).
- This product has properties and characteristics associated with chemicals detected in ground water. This chemical may leach into ground water if used in areas where soils are permeable, particularly where the water table is shallow. Therefore contain any product spills or equipment leaks and dispose of wastes according to the disposal instructions on this label.
- This pesticide is toxic to fish, aquatic invertebrates, and freshwater/estuaries/marine aquatic plants. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Runoff may be hazardous to aquatic organisms in water adjacent to treated areas.

INFORMATION

EMESTO SILVER is a fungicide seed dressing for protection against listed seedborne and soilborne diseases in potatoes and wheat.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage, disposal or cleaning of equipment.

PESTICIDE STORAGE

Store in original container away from feed and food. Store in cool, dry area. Do not store in direct sunlight. Do not allow prolonged storage in temperatures that exceed 105°F (40°C) or in temperatures that fall below 14°F (-10°C).

PESTICIDE DISPOSAL

To avoid wastes, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste facility or pesticide disposal program (often such programs are run by state or local governments or by industry).

CONTAINER HANDLING

Rigid, Non-refillable containers (equal to or less than 5 gallons)

Non-refillable container. Do not reuse or refill this container. Offer for recycling, if available. Triple rinse or pressure rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip.

Once container is rinsed, offer for recycling if available or puncture and dispose of in a sanitary landfill.

Rigid Non-refillable containers (greater than 5 gallons or 50 lbs)

Non-refillable Containers

Non-refillable containers - Do not reuse or refill this container. Refer to Bottom Discharge IBC or Top Discharge IBC, Drums, Kegs information as follows.

Bottom Discharge IBC (e.g. – Schuetz Caged IBC or Snyder Square Stackable)

Pressure rinsing the container before final disposal is the responsibility of the person disposing of the container. To pressure rinse the container before final disposal, empty the remaining contents from the IBC into application equipment or mix tank. Raise the bottom of the IBC by 1.5 inches on the side which is opposite of the bottom discharge valve to promote more complete product removal. Completely remove the top lid of the IBC. Use water pressurized to at least 40 PSI to rinse all interior portions. Continuously pump or drain rinsate into application equipment or rinsate collection system while pressure rinsing. Continue pressure rinsing for 2 minutes or until rinsate becomes clear. Replace the lid and close bottom valve.

Top Discharge IBC, Drums, Kegs (e.g.– Snyder 120 Next Gen, Bonar B120, Drums, Kegs).

Triple rinsing the container before final disposal is the responsibility of the person disposing of the container. To triple rinse the container before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container at least 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Rinse all interior surfaces. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this procedure two more times.

Once container is rinsed, offer for recycling if available or puncture and dispose of in a sanitary landfill.

Refillable Containers

Refillable container – Refer to Bottom Discharge IBC or Top Discharge IBC, Drums, Kegs information as follows. Refill this container with pesticide only. Do not reuse this container for any other purpose. Contact your Ag retailer or Bayer CropScience for container return, disposal and recycling information.

Bottom Discharge IBC (e.g. – Schuetz Caged IBC or Snyder Square Stackable)

Pressure rinsing the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To pressure rinse the container before final disposal, empty the remaining contents from the IBC into application equipment or mix tank. Raise the bottom of the IBC by 1.5 inches on the side which is opposite of the bottom discharge valve to promote more complete product removal. Completely remove the top lid of the IBC. Use water pressurized to at least 40 PSI to rinse all interior portions. Continuously pump or drain rinsate into application equipment or rinsate collection system while pressure rinsing. Continue pressure rinsing for 2 minutes or until rinsate becomes clear. Replace the lid and close bottom valve.

Top Discharge IBC, Drums, Kegs (e.g.– Snyder 120 Next Gen, Bonar B120, Drums, Kegs).

Triple rinsing the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To triple rinse the containers before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container at least 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Rinse all interior surfaces. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this procedure two more times.

Once container is rinsed, offer for recycling if available or puncture and dispose of in a sanitary landfill.

End users are authorized to remove tamper evident cables as required to remove the product from the container unless the container is equipped with one way valves and refilling or returning is planned. If this is the case, end users are not authorized to remove tamper evident cables, one way valves or clean container.

IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following Conditions, Disclaimer of Warranties and Limitations of Liability.

Treatment of highly mechanically damaged seed, or seed of known low vigor and poor quality, may result in reduced germination and/or reduction of seed and seedling vigor. Treat and conduct germination tests on a small portion of seed before committing the total seed lot to a selected chemical treatment. Due to seed quality conditions beyond the control of Bayer CropScience, no claims are made to guarantee germination of carry-over seed.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Bayer CropScience. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE MAKES NO WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of Bayer CropScience is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

LIMITATIONS OF LIABILITY: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT BAYER CROPSCIENCE'S ELECTION, THE REPLACEMENT OF PRODUCT.

NET CONTENTS:

PRODUCED FOR



Bayer CropScience

Bayer CropScience LP
P.O. Box 12014, 2 T.W. Alexander Drive
Research Triangle Park, North Carolina 27709
1-866-99BAYER (1-866-992-2937)

EMESTO SILVER (PENDING) 01/19/2016, 02/24/2016, 03/01/2016